



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2015-0035; FRL-9945-68]

Clethodim; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of clethodim in or on multiple commodities which are identified and discussed later in this document. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2015-0035, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703)

305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2015-0035 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2015-0035, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of Wednesday, May 20, 2015 (80 FR 28925) (FRL-9927-39), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4E8334) by Interregional Research Project Number 4 (IR-4), 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.458 be amended by establishing tolerances for residues of the herbicide clethodim, 2-[(1E)-1-[[[(2E)-3-chloro-2-propenyl]oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one, and its metabolites containing the 5-(2-ethylthiopropyl)cyclohexene-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulfoxides and sulphones, calculated as the stoichiometric equivalent of clethodim, in or on stevia at 12 parts per million (ppm); pome fruit group 11-10 at 0.2 ppm; stone fruit group 12-12 at 0.2 ppm; bulb onion subgroup 3-07A at 0.2 ppm; low growing berry subgroup 13-07G, except cranberry at 3.0 ppm; rapeseed subgroup 20A, except flax 0.5 ppm; sunflower subgroup 20B at 5.0 ppm; cottonseed subgroup 20C at 1.0 ppm; and fruiting vegetable group 08-10 at 1.0 ppm. Also, this notice further requests amending 40 CFR 180.458 by removing the following commodity listings: canola seed at 0.5 ppm, cotton, undelinted seed at 1.0 ppm, peach at 0.2 ppm, onion, bulb at 0.2 ppm, strawberry at 3.0 ppm, and sunflower, seed at 5.0 ppm, upon establishment of the aforementioned tolerances. That document referenced a summary of the petition prepared by Valent USA Corporation, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has made some modifications to petitioned-for crop tolerances. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for clethodim including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with clethodim follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The liver is the target organ based on repeated dosing by either oral or dermal routes in rats, mice, and dogs. The observed liver effects are characterized by increased liver weights,

clinical chemistry changes, and centrilobular hepatic hypertrophy. Most of the liver effects that occurred at or below 100 milligrams/kilogram body weight (mg/kg bw) were considered as adaptive effects and not adverse. Decreased body weight was also a common finding across studies and species. In the 1-year dog oral toxicity study, hematological changes such as increased platelet and leukocyte counts were also noted.

Developmental effects were not present in rabbits; the rat developmental toxicity study showed reduced fetal body weights and an increase in the incidence of delayed ossification of the lower vertebrae at the same dose where maternal toxicity was found. Neither reproductive nor offspring effects were seen in the 2-generation rat reproduction study. Therefore, the data did not show an increased susceptibility in the young. The clethodim database also showed no potential for neurotoxicity or immunotoxicity.

The rat and mouse carcinogenicity studies did not show treatment-related increases in tumor incidence. Clethodim is not genotoxic and is classified as “not likely to be carcinogenic to humans.”

Specific information on the studies received and the nature of the adverse effects caused by Clethodim as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document”, Clethodim. Human Health Aggregate Risk Assessment for the Proposed New Uses on Stevia, Pome Fruit Group 11-10, Stone Fruit Group 12-12, Bulb Onion Subgroup 3-07A, Low Growing Berry Subgroup 13-07G, (except Cranberry); Rapeseed Subgroup 20A (except Flax Seed), Sunflower Subgroup 20B, Cottonseed Subgroup 20C, and Fruiting Vegetable Group 8-10, pages number 29 through 34 in docket ID number EPA-HQ-OPP-2015-0035.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see

<http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides>.

A summary of the toxicological endpoints for clethodim used for human risk assessment is shown in Table 1 of this unit.

Table 1.--Summary of Toxicological Doses and Endpoints for Clethodim for Use in Human Health Risk Assessment

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (All populations)	NOAEL = 100 mg/kg/day	Acute RfD = 1 mg/kg/day	Acute neurotoxicity studies- rats LOAEL = 1,000 mg/kg based on clinical observation from two

	$UF_A = 10x$ $UF_H = 10x$ FQPA SF = 1x	aPAD = 1 mg/kg/day	acute neurotoxicity studies (one study was conducted in 2006 and another was completed in 2012). The clinical observation included decreased spontaneous activity, ruffled fur, head tilt, and hunched posture.
Chronic dietary (All populations)	NOAEL= 30 mg/kg/day $UF_A = 10x$ $UF_H = 10x$ FQPA SF = 1x	Chronic RfD = 0.3 mg/kg/day cPAD = 0.3 mg/kg/day	Carcinogenicity study-mice, LOAEL = 150 mg/kg/day based on reduced survival; decreased red cell mass; and increased incidences of bile duct hyperplasia, of pigmentation of the liver, and of foci of amphophilic macrophages in the lung.
Incidental Oral Short-Term (1-30 days)	NOAEL = 75 mg/kg/day $UF_A = 10X$ $UF_H = 10X$ FQPA SF=1X	LOC for MOE = 100	90-day oral toxicity-dogs LOAEL = 125 mg/kg/day based on increased absolute and relative liver weights, and histological changes characterized by cytoplasmic vesiculation and vacuolation of the central lobular hepatocytes in both sexes.
Inhalation Short-Term (1 to 30 days)	NOAEL = 75 mg/kg/day $UF_A = 10X$ $UF_H = 10X$ FQPA SF = 1X	LOC for MOE = 100	90-day oral toxicity-dogs LOAEL = 125 mg/kg/day based on increased absolute and relative liver weights, and histological changes characterized by cytoplasmic vesiculation and vacuolation of the central lobular hepatocytes in both sexes.
Cancer (Oral, dermal, inhalation)	Clethodim is classified as "Not Likely" to be carcinogenic based no treatment-related increase in tumor incidence in rat and mouse carcinogenicity studies.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. NOAEL = no-observed-

adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to clethodim, EPA considered exposure under the petitioned-for tolerances as well as all existing clethodim tolerances in 40 CFR 180.458. EPA assessed dietary exposures from clethodim in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for clethodim. In estimating acute dietary exposure, EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID), Version 3.16, which incorporates 2003-2008 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA conducted unrefined acute dietary analyses assuming tolerance-level residues for all commodities and 100 percent crop treated (PCT). Unless tolerances were established for processed commodities, DEEM version 7.81 default processing factors were assumed.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the DEEM-FCID, Version 3.16, which incorporates 2003-2008 food consumption data from the USDA's NHANES/WWEIA. As to residue levels in food, EPA conducted unrefined chronic dietary analyses assuming tolerance-level residues for all commodities and 100 PCT. Unless tolerances

were established for processed commodities, DEEM version 7.81 default processing factors were assumed.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that clethodim does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk was not conducted.

iv. *Anticipated residue and percent crop treated (PCT) information*. EPA did not use anticipated residue and/or PCT information in the dietary assessment for clethodim. Tolerance-level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water*. The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for clethodim in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of clethodim. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at:

<http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide>.

Based on the First Index Reservoir Screening Tool (FIRST) and Pesticide Root Zone Model Ground Water (PRZM GW) models, the estimated drinking water concentrations (EDWCs) of clethodim for acute exposures are 330 parts per billion (ppb) for surface water and 1,430 ppb for ground water.

For chronic exposures for non-cancer assessments are estimated to be 137 ppb for surface water and 1,150 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

For acute dietary risk assessment, the water concentration value of 1,430 ppb was used to assess the contribution to drinking water.

For chronic dietary risk assessment, the water concentration of value 1,150 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Clethodim is currently registered for the following uses that could result in residential exposures: in and around ornamental plant beds, landscaped area, trees, and ground covers (mulch). There are no residential uses associated with proposed new uses. EPA has previously assessed clethodim residential exposure using the following assumptions: short-term residential handler inhalation exposures represent the “worst case” high-end exposure. Because a dermal hazard was not identified, residential handler and post-application dermal risk assessments were not conducted. No other post-application exposures were assessed either because the potential for exposure via non-dietary ingestion for young children is unlikely due to the limited residential uses for clethodim products. The extent to which young children engage in the types of activities associated with these areas (i.e., ornamental landscapes) or utilize these areas for prolonged periods of play is low. No intermediate-term or chronic exposures are expected from the currently registered residential uses.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at: <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide>.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or

revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found clethodim to share a common mechanism of toxicity with any other substances, and clethodim does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that clethodim does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at: <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There is no evidence of increased susceptibility of fetuses as compared to maternal animals following *in utero* and/or postnatal exposure to clethodim in the developmental toxicity studies in rats or rabbits, and no increased sensitivity in pups as compared to adults in the 2-generation rat

reproduction toxicity study. There are no residual uncertainties concerning prenatal and postnatal toxicity and no neurotoxicity concerns.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

- i. The toxicity database for clethodim is complete.
- ii. There is no indication that clethodim is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.
- iii. There is no evidence of increased susceptibility of fetuses as compared to maternal animals following *in utero* and/or postnatal exposure to clethodim in the developmental toxicity studies in rats or rabbits, and no increased sensitivity in pups as compared to adults in the 2-generation rat reproduction toxicity study. In the rat developmental study, reduced ossification seen at the same dose that resulted in maternal toxicity is considered secondary to reduced maternal body weight, and is not considered qualitative susceptibility. There are no residual uncertainties concerning prenatal and postnatal toxicity and no neurotoxicity concerns.
- iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to clethodim in drinking water. Post application exposure of children and incidental oral exposures to toddlers are expected to be negligible. All exposure estimates are based on conservative assumptions that will not underestimate the exposure and risks posed by clethodim.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. Acute exposure is not expected for the residential exposure pathway. Therefore, the acute aggregate risk would be equivalent to the acute dietary exposure estimates.

Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to clethodim will occupy 29% of the aPAD for all infants <1 year old, the population group receiving the greatest exposure.

2. *Chronic risk.* There are no chronic residential exposure scenarios. Therefore, the chronic aggregate risk would be equivalent to the chronic dietary exposure (food and drinking water) estimate. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to clethodim from food and water will utilize 30% of the cPAD for all infants <1 year old, the population group receiving the greatest exposure.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Clethodim is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to clethodim. Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the

combined short-term food, water, and residential exposures result in the short-term aggregate risk estimate for adults ages 20-49 is a MOE of 2,200. Because EPA's level of concern for clethodim is a MOE of 100 or below, this MOE is not of concern.

4. *Intermediate-term risk.* An intermediate-term adverse effect was identified; however, clethodim is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for clethodim.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, clethodim is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to clethodim residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodologies are available: FDA Multiresidue Methods, gas chromatography/flame photometric detection in the sulfur mode (GC/FPD-S) and gas chromatography method with mass selective detection (GC/MSD).

These methods have been adequately validated for the analyses of residues of clethodim in/on crop matrices.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has established MRLs for clethodim in or on onion bulb and garlic at 0.5 ppm, tomato at 1 ppm, rapeseed at 0.5 ppm, sunflower seed at 0.5 ppm, and cotton seed at 0.5 ppm. The U.S. tolerances for rapeseed subgroup 20A, fruiting vegetables crop group 8-10, and onion, bulb, subgroup 3-07A are harmonized with the Codex MRLs for rapeseed, tomato, and bulb onion and garlic, respectively.

However, the US tolerances for sunflower subgroup 20B and cottonseed subgroup 20C are not harmonized with the corresponding Codex MRLs for sunflower seed and cotton seed since the MRL values are lower than the US tolerances. The U.S. tolerances cannot be lowered to harmonize because doing so could result in residues above the tolerances when following the U.S. approved label directions.

C. Revisions to Petitioned-For Tolerances

The Agency made changes to the naming of certain petitioned-for commodities to reflect the current commodity definitions and significant figures used by the Agency. Although the petitioner requested a tolerance on stevia only, EPA established a tolerance on stevia, dried leaves because the dried commodity represents stevia that will be found in the U.S. trade market. Moreover, the Agency is removing certain commodities from the table at § 180.458(a) in order to eliminate redundancies upon the establishment of new crop group tolerances that were not identified in the petition: mustard, seed at 0.5 ppm, safflower, seed at 5.0 ppm, sesame, seed at 0.35 ppm, vegetable, fruiting group 8 at 1.0 ppm.

V. Conclusion

Therefore, tolerances are established for residues of clethodim, 2-[(1E)-1-[[[(2E)-3-chloro-2-propenyl]oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one, and its metabolites containing the 5-(2-ethylthiopropyl)cyclohexene-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulfoxides and sulphones, calculated as the stoichiometric equivalent of clethodim, in or on berry, low growing, subgroup 13-07G, except cranberry at 3.0 ppm; cottonseed subgroup 20C at 1.0 ppm; fruit, pome, group 11-10 at 0.20 ppm; fruit, stone, group 12-12 at 0.20 ppm; onion, bulb, subgroup 3-07A at 0.50 ppm; rapeseed subgroup 20A, except flax seed at 0.50 ppm; stevia, dried leaves at 12 ppm; sunflower subgroup 20B at 5.0 ppm; and vegetable, fruiting, group 8-10 at 1.0 ppm. EPA is also removing the following established tolerances that are superseded by this action: Canola seed, at 0.50 ppm; cotton, undelinted seed at 1.0 ppm; mustard, seed at 0.50 ppm; peach at 0.20 ppm; onion, bulb at 0.20 ppm; strawberry at 3.0 ppm; safflower, seed at 5.0 ppm; sesame, seed

at 0.35 ppm; sunflower, seed at 5.0 ppm; vegetable, fruiting group 8 at 1.0 ppm. Finally, as a housekeeping measure, the Agency is removing two individual tolerances that are subsumed within other crop group tolerances contained in §180.458: Bean, dry, seed at 2.5 ppm is covered by the entry for vegetable, legume, group 6, except soybean at 3.5 ppm and potato at 0.5 ppm is covered by the entry for vegetable, tuberous and corm, subgroup 1C at 1.0 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power

and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 28, 2016.

Susan Lewis,
Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.458, in the table in paragraph (a):

- a. Remove the entry for “Bean, dry, seed;”
- b. Add alphabetically an entry for “Berry, low growing, subgroup 13-07G, except cranberry;”
- c. Remove the entry for “Canola seed;”
- d. Add alphabetically an entry for “Cottonseed subgroup 20C;”
- e. Remove the entry for “Cotton, undelinted seed;”
- f. Add alphabetically entries for “Fruit, pome, group 11-10” and “Fruit, stone, group 12-12;”
- g. Remove the entries for “Mustard, seed” and “Onion, bulb;”
- h. Add alphabetically an entry for “Onion, bulb, subgroup 3-07A;”
- i. Remove the entries for “Peach” and “Potato;”
- j. Add alphabetically an entry for “Rapeseed subgroup 20A, except flax seed;”
- k. Remove the entries for “Safflower, seed,” “Sesame, seed,” and “Strawberry;”
- l. Add alphabetically an entry for “Stevia, dried leaves;”
- m. Remove the entries for “Sunflower, seed,” and “Vegetable, fruiting group 8;” and
- n. Add alphabetically the entries for “Sunflower subgroup 20B” and “Vegetable, fruiting, group 8-10.”

The additions read as follows:

§ 180.458 Clethodim; tolerance for residues.

(a) * * *

Commodity	Parts per million
* * *	* * *
Berry, low growing, subgroup 13-07G, except cranberry	3.0
* * *	* * *
Cottonseed subgroup 20C	1.0
* * *	* * *
Fruit, pome, group 11-10	0.20
Fruit, stone, group 12-12	0.20
* * *	* * *
Onion, bulb, subgroup 3-07A	0.50
* * *	* * *
Rapeseed subgroup 20A, except flax seed	0.50
* * *	* * *
Stevia, dried leaves	12
* * *	* * *
Sunflower subgroup 20B	5.0
* * *	* * *
Vegetable, fruiting, group 8-10	1.0
* * *	* * *

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